

REGULATING FOOD SAFETY AND QUALITY

There are several federal agencies that play significant roles in regulating food safety and quality in the United States. The Food and Drug administration (FDA), the Food Safety and Inspection Service (FSIS) of the U. S, Department of Agriculture, and the Environmental Protection Agency (EPA) are the primary bodies concerned with food safety. Other agencies are also involved in food safety regulation. For example, in addition to FDA, the Department of Transportation regulates how food and food ingredients are transported; the National Marine Fisheries Service of the U.S. Department of Commerce administers a voluntary seafood inspection program for processing facilities. This is a fee-for-service program using organoleptic (e. g., sight and smell) inspection.

The U.S. Department of Agriculture (USDA) has inspection and regulatory jurisdiction over meat, poultry, and egg products. The department works with FDA to form the backbone of the federal food safety apparatus. The principal USDA agency in charge of food safety is the Food Safety and Inspection Service (FSIS). Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), FSIS exercises regulatory jurisdiction over essentially all meat and poultry products offered for sale in the U.S. In addition, under the Department of Agriculture Re-Organization Act, regulatory jurisdiction for egg inspection was transferred to FSIS from the Agricultural Marketing Service. The distinctive feature of FSIS regulation is that it maintains at least a daily presence in all establishments. For companies slaughtering livestock and birds, an FSIS veterinarian conducts an ante-mortem inspection to detect diseased or disabled animals. After slaughter, every single carcass is again visually inspected to detect disease or abnormalities.

The EPA was created by Congress in 1970 and its role in food safety regulation in the United States is based upon its mandate regarding water quality and to regulate pesticides that may be used in or on food crops and food-producing animals, including establishing tolerances for pesticides residues used on raw agricultural commodities and processed food products. While it is EPA that registers pesticides and establishes tolerances, it is FDA and USDA that enforce those tolerances.

FDA exercises regulatory jurisdiction over all food products except meat and poultry. FDA's primary food safety regulatory authority comes from the Federal Food Drug and Cosmetic Act (FDCA) and its various amendments. Other statutes (for example, the Public Health Service Act) also provide specific safety-related regulatory authority.

The FDCA is intended to assure the consumer that foods are pure and wholesome; safe to eat and produced under sanitary conditions, and that all labeling and packaging is truthful, informative, and not deceptive. The FDCA prohibits distribution in the United States, or importation, of articles that are adulterated or misbranded. The term "adulterated" includes products that are defective, unsafe,

filthy, or produced under insanitary conditions. "Misbranded" includes statements, designs, or pictures in labeling that are false or misleading, and failure to provide required information in labeling.

Inasmuch as the peanut butter at issue is the regulatory responsibility of the FDA, this document will focus on the FDA and its documented policies and procedures.

The primary authority FDA possesses to inspect facilities is § 704 of the FDCA. This provision grants FDA authority to inspect at reasonable times and within reasonable limits and in a reasonable manner "food establishments-including growing, handling, manufacturing, warehousing and shipping facilities-and their operations. This authority would encompass entry into the facility; viewing of equipment; sampling of finished goods, unprocessed raw materials, and in-process materials; and collection of labeling for review to ensure compliance with applicable labeling laws and regulations.

Section 704(b) of the FDCA requires the FDA investigator to give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices he or she observes which, in his or her judgment, indicate that any food, drug, device or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. This report of inspectional observations is commonly known as the FDA-483, Inspectional Observations.

FDA personnel are authorized under § 704(c) of the FDCA to collect samples of finished and unfinished products, packaging materials and ingredients. They are required to provide a receipt describing the physical sample collected, but they do not issue receipts for labeling or promotional materials. If the sample(s) collected are analyzed by FDA for the purpose of ascertaining whether such food consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food, a copy of the analytical results must be provided to the company.

Regulatory Follow-Up

Where an FDA inspection uncovers violations of the FDCA, the agency is authorized to initiate a broad range of enforcement actions against the company in question. These include issuing a Warning Letter; civil seizure against a specific lot of goods to remove them from the channels of commerce; judicial injunction, and criminal prosecution. FDA may also request a company to conduct a product recall to remove or correct a marketed product that FDA considers to be in violation of the law and against which the agency would otherwise initial legal action. Technically, product recalls are voluntary actions, but the agency can invoke the regulatory actions mentioned to remove a product they consider to be in violation of

the FDCA. Generally companies conduct recalls upon FDA request to prevent regulatory action against the goods and possible adverse publicity.

Good Manufacturing Practices

The term “good manufacturing practices” is widely used in the industry but there is no codified definition. To regulators the term is generally considered to mean a system of policies, procedures and documentation, written or analytical, to ensure the product(s) produced have the identity, strength, quality, purity and composition which it purports or is represented to have.

Under § 701 of the FDCA, the FDA has authority to promulgate regulations for the efficient enforcement of the FDCA. Several regulations have been published including good manufacturing practices (GMPs) for food which is codified at 21 CFR Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. The criteria and definitions in this part apply in determining whether a food is adulterated within Sections 402(a) (3) or 402(a) (4) of the FDCA. These regulations state that a food is adulterated if it “consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food” or “if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.” The food GMP regulations describe the methods, equipment, facilities and controls for producing process food, but they are broadly written and general in nature to allow individual variation by manufacturers to implement the requirements that best suited their needs in ensuring that foods are not adulterated within the meaning of the FDCA.

The following food industry specific GMPs have been published by FDA:

1. 21 CFR Part 106, Infant Formula Quality Control Procedures
2. 21 CFR Part 113, Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers
3. 21 CFR Part 114, Acidified Foods
4. 21 CFR Part 120, Hazard Analysis and Critical Control Point (HACCP) Systems
5. (Commonly known as juice HACCP)
6. 21 CFR Part 123, Fish and Fishery Products
7. 21 CFR Part 129, Processing and Bottling of Bottled Drinking Water

The most widely recognized method for controlling food safety hazards is the Hazard Analysis Critical Control Point (HACCP) system. While HACCP is perceived as the newest hazard control method, it was developed in the 1970s to ensure safety of food products consumed by astronauts during space travel.

In essence, HACCP is a methodical system that ensures food safety by identifying specific chemical, biological or physical hazards in advance of processing so that

those hazards may be controlled. Hazards are identified through a comprehensive review of a processor's specific operation. The processor then determines what points in the process are critical to controlling identified, "unacceptable" hazards – i.e., critical control points. Once critical control points are determined, effective preventive measures are developed and implemented by the processor; the efficacy of the controls is continually monitored, using an effective recordkeeping system.

The production of safe food products requires that the HACCP system be built upon a solid foundation of prerequisite program including GMP compliance, effective sanitation policies and procedures, adequate facilities, employee personal hygiene, training, quality raw materials, and adequately maintained and calibrated equipment.

Investigation of Foodborne Outbreaks

The FDA uses investigative techniques to assist in determining the cause of a food-borne outbreak or illness.

The information presented describes the standard methods for data gathering and evaluation of food-borne outbreaks and illnesses.

Cooperation With Other Agencies

In order to provide for more efficient use of FDA and other agency manpower and resources and to prevent duplication of effort, FDA and various agencies have entered into formal or informal agreements and/or understandings. These specify areas in which each will assume primary responsibility.

State and Local officials have extensive regulatory authority over firms in their area regardless of the interstate movement or origin of the food products involved. Joint FDA-State or Local inspections and investigations are frequently conducted.

The FDA has a Memorandum of Understanding with the Center for Disease Control regarding exchange of information and coordination of actions.

One of FDA's functions is to assist Local, State, and Federal agencies in conducting investigations, collecting samples, and conducting plant inspections, if warranted. The Center for Disease Control (CDC) and the State agency frequently take the lead in a food-borne outbreak or illness.

Investigation of Food-borne outbreaks and illnesses

Epidemiological investigative techniques have been established to assist in determining the cause of a food-borne outbreak or illness.

Investigator kits with proper equipment are maintained in each FDA office to facilitate immediate investigation of food-borne outbreaks.

If the alert or complaint indicates a large outbreak, the FDA servicing laboratory is immediately notified that samples will probably be collected and an approximate time is given when the samples are expected to arrive at the laboratory. This will assist laboratory managers planning work schedules, equipment, and supplies.

Interviews

A health professional, hospital personnel, or an ill person may report suspected cases of food-borne illness. Regardless of the source, the diagnosis must be verified by a thorough case history and, if possible, by examination of appropriate samples and clinical specimens. This verification is by public health professionals.

The FDA investigator during his/her interview must phrase questions so that the person(s) interviewed will describe their illness and the foods and events which they feel were associated with it in their own way.

Information is obtained about all meals and snacks eaten seventy-two hours before the onset of illness. The food, even the meal, which precipitated the illness, might not be obvious. The type of illness will sometimes give a clue.

If the first and predominant symptoms are nausea and vomiting, the investigator's questions concentrate on foods eaten recently.

If the first and predominant symptoms are diarrhea and abdominal cramps, foods eaten six to twenty four hours before onset of illness are suspect.

If diarrhea, chills, and fever predominate, foods eaten twelve to seventy-two hours before onset of illness are suspect.

The above symptoms relate to common food borne illnesses. The more unusual illnesses often present different clinical patterns.

This detailed interview approach is used with every person who has been identified in the initial complaint or alert even though some may not have been ill, until the agency has sufficient information to determine whether there is a food borne disease outbreak.

Sampling Procedures

During the investigation of the food borne or illness outbreak the FDA Investigator often works with other health officials in collecting samples of items which may be associated with the outbreak.

The Investigator uses data from an attack-rate table to determine which of the foods implicated are the most suspect and will collect samples of those foods.

The Investigator determines supplier, distribution, and code information on packaged foods to aid any investigation that might be made of the same lot in distribution channels.

The remaining portions of all suspect foods and parent stocks of suspect foods are collected by the Investigator.

Samples of suspect food containers such as cans, bottles, and materials used in the preparation and storage of the suspect food, utensils, table scrapings, and food residues from equipment such as slicing machines, grinders, cutting boards are collected by the Investigator and his/her team.

Samples of vomitus and stools of victims, swabs of nasal and throat passages, or open sores or lesions of food handlers may be collected by a physician or individuals trained in the technique of collecting and preserving these samples.

If the suspect food is a commercial product the original container is examined for coding information to identify the place and time of processing. FDA may notify all agencies responsible for regulating the products alleged or suspected to have caused the illness. The Investigator will usually collect additional samples bearing the same code number for analyses for microorganisms, toxins, seam defects, vacuum leaks, or other conditions. The Investigator will immediately inform the analyzing laboratory of the type and number of samples, and discuss methods to preserve and transport samples, time of arrival, and the person who will receive the shipment.

Outbreak Determination

An outbreak is an incident in which two or more individuals have the same disease, have similar symptoms, or excrete the same pathogens; and there is a time, place, and/or person association between these individuals. A food borne disease outbreak is one in which a common food has been ingested by such individuals.

Sometimes it will be obvious from an initial report that a food borne disease outbreak has occurred simply because of the number individuals displaying certain symptoms at or near the same time.

Many complaints, however, involve illness in only one or two individuals, and determining that a particular food was responsible, or that its consumption and the onset of illness was only coincidental, is often difficult.

If additional complaints connected with the same food or eating at the same place are received, food is almost certainly involved. A food-related or enteric disease alert/complaint logs assists in determining if similar complaints have been received.

Time, place, and person associations must always be considered when investigating a possible food borne outbreak.

Assistance

If the outbreak affects a large number of individuals the Investigator may need assistance from a team consisting of an epidemiologist, microbiologist or chemist, sanitarian, and others in order to make a sufficiently detailed food borne illness investigation.

Additional Case History Interviews

The Investigator will seek and interview additional individuals both ill and well, who had time, place, or person associations with the identified cases.

Further contact may be other health agencies, hospital emergency rooms, poison control centers, and local physicians to find additional cases. At this stage of the investigation, interviews can be accelerated by reviewing the event itself to stimulate each individual's recall. The Investigator will inquire about specific symptoms known to be common to the suspected syndrome and mention the food involved in the event or meal.

The number of individuals to be interviewed depends on the proportion of individuals who are probably affected.

Establishment Investigation

When a food borne outbreak is reported and an establishment must be inspected, the FDA Field office will assign a team leader and assemble a team of investigators, microbiologists, and other specialists to inspect the plant as soon as possible.

The team leader will inform the person in charge of the reason for the inspection. The team will make a comprehensive inspection of the facility to determine if the firm is in compliance with Good Manufacturing Practices regulations; attempt to determine if the product became adulterated because of poor raw material quality, dirty equipment, insect, rodent, or bird filth, a leaking roof, poor employee practices, poor sanitation and housekeeping, or some other contaminant.

Evidence will be gathered by observation of the manufacturing operations, collection of in-line samples and samples of raw materials and finished products, photographs, and other evidence that may document a possible adulteration of the products manufactured by the facility.

At the conclusion of the inspection if GMP violations have been found an FD-483 (Inspectional Observations) will be issued to the person in charge, the observations

discussed, and the FDA team leader will ask when the violations will be corrected. If samples are collected, form FD-484 (Receipt for Samples) will be issued describing the samples collected during the investigation.

Samples collected during the investigation are sealed with an FDA seal, refrigerated or frozen, if necessary, and delivered to the FDA servicing laboratory as soon as possible for analysis. The samples are identified with the FDA sample number, investigator's initials, and date the sample was collected. The FDA seal applied to the sample bears the sample number, investigator signature, and date. When the samples arrive at the FDA laboratory, a receiving employee maintains the chain of custody by logging in a description of the sample, the sample number, investigator name, and date on the sample receipt log.

Possible Contamination Source

The raw materials may be contaminated with pathogenic bacteria and may have contaminated the equipment and/or atmosphere in the facility.

Swabbing food contact surfaces of equipment that had contact with the suspect raw material may establish links in the transmission of contamination. This is especially helpful if a common utensil or piece of equipment is used for raw and cooked food.

Samples of swabs from air filters, drains, vacuum sweepings, food scrap piles, dried deposits on equipment, and dead ends of pipe lines may reflect the presence of pathogenic organisms that previously were in the facility.

The Investigator will evaluate the cleanliness, manner, and frequency of cleaning equipment. He/she will also look for opportunities and possible routes of cross-contamination between raw and cooked foods.

Ingredients may be the initial source of pathogens; therefore, the Investigator must determine which were added before and which were added after any cooking or heat treatment.

Workers may be a source of food borne pathogens. Employee practices such as proper hand washing and sanitizing of hands will be observed by the Investigator.

The Investigator will also observe employees for any sign of pimples, minor skin inflammation, boils, and infected cuts or burn on unclothed areas of the body.

**Observations from Audit of ConAgra Foods facility, 101 Seabrook
Drive, Sylvester, Georgia 31791
April 13, 2007**

Background

This audit was done by appointment and made as a follow-up to an outbreak of Salmonella serotype Tennessee infection involving over 425 individuals from 44 States. Epidemiological investigations by the U. S. Food & Drug Administration (FDA) and the Center for Disease Control (CDC) implicated Peter Pan and Great Value brands peanut butter manufactured by the ConAgra Foods, Inc., facility located in Sylvester, Ga.

In addition, product testing confirmed the presence of the outbreak strain of Salmonella Tennessee in opened jars of peanut butter obtained from ill individuals. We are not aware to date of any findings of Salmonella cultured from environmental samples collected from the manufacturing plant or unopened jars of peanut butter collected from the firm, the market place, or individuals.

During this audit, the firm was not operating and appeared not to have done so for some time.

Good housekeeping practices and plant sanitation practices were found to be deficient as the food manufacturing facility was found to be dirty in many areas with heavy product residues found on and inside equipment, black mold was observed on the wall in a manufacturing room, there were dark moisture stains on the overhead steel roof supports located above the Line B filler and the Institutional filler, product residues were found on the underside of the stainless steel protective shield under which uncapped jars of filled peanut butter pass.

Some areas appeared to have been recently painted as evidenced by the top half of the walls in an electrical room which had been painted while heavy brown stains on the wall below the new paint showed evidence of water that had run down the walls, apparently from a roof leak.


Several walls in the facility were observed to be soiled with a yellowish-brown discoloration, with heavy brown stains running down the walls from ceiling to floor. These stains apparently caused by the roof leaking were found in most areas of the plant, to include above the packaging lines.

Evidence of rodent activity in the form of a dead rodent in the manufacturing area, rodent excreta pellets, live Confused Flour beetles, live Sawtooth beetles, live moths, live fruit flies, and dead cockroaches were found in various locations of the plant.

Live beetles and moths were found on the inside of manufacturing equipment.

Numerous Good Manufacturing Practices violations were found during the limited Audit. The Good Manufacturing Practices violations found during the Audit could result in the adulteration of food products manufactured by the facility.


Donald F. Fernholz
Senior Consultant/Auditor
EAS Consulting Group


Carl C. Reynolds
Senior Consultant/Auditor
EAS Consulting Group